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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,004	02/08/2006	Francesca Ghigini	41622/AJ/CD	5829

7590 10/30/2008
Modiano & Associati
Via Meravigli 16
Milano, 20123
ITALY

EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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10/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,004	Applicant(s) GHIGINI, FRANCESCA	
	Examiner CHRISTIAN Y. JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive amendment filed on July 24, 2008. Claims 11-20 are pending in instant application. The amendments to claims 11 and 17 are acknowledged by the examiner.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 11-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (USP #6,332,867) in view of Caro et al. (US 2002/0095090).

4. As to claim 11, Chen teaches a device for detecting arterial pressure with high measurement precision (Abstract). The device comprises a cuff with inflatable chamber (Fig. 2, 30) adapted to be placed around the arm of a patient (col 5, lines 21-24), means for introducing air to inflate said cuff (Fig. 2, 32), and decompression means adapted to decompress said inflatable chamber (Fig. 2, 34). The device further comprisesg means adapted to detect and store all the sphygmie pulses generated by the arterial pulsation and to identify the pulses that correspond to appearance and disappearance of wrist beat (Fig. 2, 15, and Fig. 1, 22), detected by means of a technique for detecting sphygmie pulses generated by arterial pressure (Fig. 2, 38). Chen fails to teach intervention of an operator to detect the sphygmie pulses and of the operator for a subsequent subjective judgment of said sphygmie pulses. Caro teaches monitoring for determining a patient's physiological parameter, such as blood pressure with a

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calibration device. Caro further teaches that a manual measurement could be input in place of an automated sphygmomanometry entry for a calibration signal ([0047]). As such, it would have been obvious to one of ordinary skill to recognize the use of an operator, similar to that of Caro, in order to make a subjective judgment of the detected pulses with a device similar to that of Chen.

5. As to claim 12, Chen teaches the decompression means of said inflatable chamber comprise a valve for providing constant and time-controlled decompression (Fig. 2, 34).

6. As to claim 13, Chen teaches the discharge means adapted to completely and instantaneously discharge the inflatable chamber of said cuff (Fig. 2, 34).

7. As to claim 14, Chen teaches the means for detecting and storing the sphygm pulses are connected to data storage means (Fig. 1, 22) , which are adapted to store the chart of the sphygm pulses (col 7, lines 38-42).

8. As to claim 15, Chen teaches a display that is adapted to display detected levels of pressure and levels of sphygm intensity of the pulsations (Fig. 4, 48).

9. As to claim 17, Chen discloses the invention substantially as claimed. Chen teaches a method for detecting arterial pressure (Abstract), comprising the steps of: pumping air into a cuff provided with an inflatable chamber (col 6, lines 22-27); decompressing said inflatable chamber (col 6, lines 27-29); detecting, sphygm pulses that correspond respectively to the appearance and disappearance of the wrist beat (col 6, lines 45-47) identifying, among said sphygm pulses, the ones that correspond to the appearance and disappearance of the pulse beat, detected by means of a stethoscope.

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Chen fails to teach an operator using a stethoscope and the storage of the chart of all the pulses. While Chen teaches a storage means, it fails to explicitly teach storage of all the charts. However, Caro teaches a monitoring for determining a patient's physiological parameter such as blood pressure with a calibration device. Caro teaches that a manual measurement could be input in place of an automated sphygmomanometry entry for a calibration signal ([0047]). In addition, Caro teaches that the traditional manual method of measuring blood pressure is with a stethoscope ([0004]). Furthermore, Caro teaches the storage of the waveform information which is equivalent to storing the chart. As such, it would have been obvious for one of ordinary skill in the art to modify the Chen by manual operation of an operator using a stethoscope and a storage means to store all of the chart data of the pulses generated in order to allow for an accurate measurement and storage of data in the event that the automated determination method is obviously in error or malfunctioning in the operator's judgment.

10. As to claim 18, Chen teaches the step of performing the decompression of said inflatable chamber comprises performing decompression at a controlled and constant rate (col 6, lines 29-31. Chen discloses a cuff that is "controllably deflated by opening evacuation valve under the control of the microprocessor". It is the examiner's position that a constant rate of deflation is inherent to Chen's disclosure).

11. As to claim 19, Chen teaches the step of storing said sphygmic pulses generated by arterial pulsation, in order to allow subsequent analysis of the chart of sphygmic pulses, in order to determine assuredly the pulses that actually correspond to the maximum and minimum values of arterial pressure (col 7, lines 38-42).

12. Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (USP #6,332,867) and of Caro et al. (US 2002/0095090), and further in view of Barker (USP #5,201,320).

13. As to claim 16, Chen and Caro do not disclose a button to be pressed by an operator when the operator detects pulses corresponding to systolic or diastolic pressures.

Barker teaches buttons or switches 32 and 34 (col. 4, lines 39-43) for the purpose of marking off the pressure readings of systolic and diastolic pressures.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Chen and Caro with the button apparatus taught by Barker in order to simplify operation of the device, to allow the operator to concentrate on determining only the points of systolic or diastolic pressure, without needing to account for the actual pressure readings themselves.

14. As to claim 20, Chen and Caro do not disclose a step of pressing on a button at sphygmie pulses corresponding to systolic and diastolic pressure are detected, such that the pressures are "marked" on a digital scale of the device.

Barker teaches buttons or switches 32 and 34 (col. 4, lines 39-43) for the purpose of marking off the pressure readings of systolic and diastolic pressures. In addition, Barker discloses a first unit 31 which contains two displays 28 and 30 which display the pressure readings at the systolic and diastolic pressure, thus "marking" the pressures.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Chen and Caro with the step of pressing buttons that "mark" the systolic and diastolic pressure points as taught by Barker in order to simplify operation of the device, to allow the operator to concentrate on determining only the points of systolic or diastolic pressure, without needing to account for the actual pressure readings themselves.

Response to Arguments

10. Applicant's arguments filed July 24, 2008 have been fully considered but they are not persuasive. Applicant has argued that a microprocessor controlled opening of the discharge valve as taught by Chen is different from a constant rate of discharge. The examiner respectfully disagrees. Most sphygmomanometers by design utilize a constant rate of discharge, a norm for many decades. The fact that Chen does not disclose the specific type of discharge is indicative that Chen intends for the accepted norm of a constant rate of release, in contrast to the more dynamic or variable types which are utilized to save measurement time that are much more recent. As such, the rejection is maintained.

11. Applicant's remaining arguments with respect to claims 11-20 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is

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(571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CJ
/C. Y. J./
Examiner, Art Unit 3735
10/25/08

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735